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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,656	09/18/2001	Charles A. Nicolette	GZ 2096.00	1157
7590	05/11/2005		EXAMINER	
GENZYME CORPORATION 15 PLEASANT STREET CONNECTOR P.O. BOX 9322 FRAMINGHAM, MA 01701-9322			MYERS, CARLA J	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 05/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/955,656	NICOLETTE ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 February 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-11 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-11 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 18 September 2001 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 22, 2005 has been entered.

2. Applicants arguments and amendments set forth in the response of February 22, 2005 have been fully considered. In view of the amendment to the claims, the previous grounds of rejection are withdrawn. However, the following new grounds of rejection are applied to the claims as amended. This action is made non-final.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10 are indefinite and vague because it is unclear as to what is intended to be the relationship between the step of binding the serum to a cell or tissue and the remainder of the claim. The claims include a step of binding serum to a cell or tissue but do not state how this step is utilized to identify the polypeptide. The claims rely only

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a comparison step of 2 lists in order to identify a polypeptide that correlates with a phenotype. It is unclear as to the relevance of the binding step, since the claimed method of identifying the polypeptide does not particularly appear to require or involve the binding of the serum to a cell or tissue.

Claims 1-11 are indefinite because it is unclear as to how one would identify a polypeptide common to both lists since the first list consists of genes and the second list consists of polypeptide characteristic data – such as mass or peptidase digestion pattern. Therefore, the comparison step involves a comparison of a list of genes (list i) with a list of data (list ii). The claims do not clarify how such a comparison would result in the identification of a polypeptide common to both lists and correlated with a phenotype of interest – i.e., since neither list recites a polypeptide.

Claims 1-11 are indefinite over the first recitation of “the polypeptide correlating with a phenotype of interest” because this phrase lacks proper antecedent basis since the claim does not previously refer to a polypeptide. The claims should be amended (i.e., claims 1 and 11, line 1) to refer to “a polypeptide correlation with a phenotype of interest.”

Claims 1-11 are indefinite over the recitation of “genes differentially expressed in said cells or tissues” because the claims do not state the criteria for determining whether a gene is differentially expressed. The claims recite that the gene is differentially expressed, but do not recite what gene expression is being compared to. For example, it is unclear as to whether the claims encompass a gene that is differentially expressed in that specific cell or tissue – e.g., expressed in some of the

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cells and not others or expressed randomly at varying levels? Or is the gene expressed in the stated cell or tissue, but not expressed in a different unstated cell or tissue, or vice versa. With respect to claim 11 (and 2-10), are the genes differentially expressed in cells from the subject with a phenotype as compared to the subject without the phenotype or differentially expressed by some of the cells from the subject with the phenotype and not by other cells of the subject with the phenotype? Clarification of what is intended to be encompassed by differential expression of the genes is required.

Claims 2-5 are indefinite over the recitation of "the gene product" because this phrase lacks proper antecedent basis.

Claims 4 and 5 are indefinite because it is unclear as to how the phrase "further comprising the property of molecular weight" is intended to further modify the claims. The claims do not clearly state the relationship between molecular weight and the remainder of the claim. For instance, it is unclear as to whether this phrase refers to the fact that molecular weight is a property of the gene products of list (i) or that molecular weight is a property of the polypeptides of list (ii) or whether molecular weight is a type of data presented in list (ii) or whether the claim requires the determination of a molecular weight.

Claims 6-10 are indefinite over the recitation of "the gene product" because this phrase lacks proper antecedent basis. Further, it is unclear as to what is intended to be meant by properties of the gene product since list (ii) provides data for polypeptides but does not provide "properties of the gene product." Thereby it is unclear as to how the

recitations of "the properties of the gene product" and "property of molecular weight" are intended to further limit the claims.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Tureci (Hybridoma. 1999. 18: 23-28; cited in the IDS of 2/26/2002).

Tureci (see, e.g., page 25) teaches a method for identifying a polypeptide correlated with the phenotype of cancer wherein the method comprises: (a) binding serum from a cancer patient to cell clones; (b) binding serum from healthy controls to cell clones; (c) preparing a list (i) of polypeptides encoded by genes that are differentially expressed in the cell clone; (iv) preparing a list (ii) of polypeptides that specifically react with serum antibodies from the cancer patients; and comparing list (i) and (ii) in order to identify polypeptides common to both lists and correlated with the phenotype of cancer. Tureci also teaches that the polypeptides of list (ii) were further defined in terms of their sequence and the sequence of the gene encoding the polypeptide and in terms of their functional properties (see page 27). With respect to claims 2-5, it is a property of the polypeptides encoded by the genes that they are highly expressed in the cell clones or uniquely expressed in the cell clones and that they are specifically reactive with antibodies in the serum of the cancer patient. It is also a

property of the polypeptides that they inherently have a molecular weight. With respect to claims 6-10, the polypeptides of list (ii) are described in terms of their ability to react with the serum antibody and thereby list (ii) comprises the data of reactivity with serum antibody. It is also a property of the polypeptides of list (ii) that these polypeptides have a molecular weight and that they have 2 or more properties of, for example, an amino acid sequence, biological activities, or uniquely expressed in specific tumor types or uniquely expressed in individual cancer patients. Accordingly, the method of Tureci anticipates the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571)-272-0745.

The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the
Electronic Business Center (EBC) at (866)-217-9197 (toll-free).

Carla Myers
May 10, 2005

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER